

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS**

RANDALL GOLDMAN

Plaintiffs,

v.

ALEX AZAR, in his capacity as Secretary of the United States Department of Health and Human Services,

Defendant.

Case No. Civil Action No. 4:20-cv-00463

PLAINTIFF'S FIRST AMENDED COMPLAINT

Plaintiff RANDALL GOLDMAN brings this action against Defendant Alex Azar, in his official capacity as Secretary of the United States Department of Health and Human Services (hereinafter, "the Secretary"), to obtain injunctive relief for violation of federal law. Plaintiff makes the following allegations based on the investigation of counsel, information and belief, and on personal knowledge.

I. SUMMARY

1. This case presents a simple question: is the Secretary bound by the Supreme Court's decisions in *U.S. v. Stauffer Chemical Co.*, 464 U.S. 165 (1984) and *Astoria Federal Savings & Loan v. Solimino*, 501 U.S. 104 (1991) such that collateral estoppel can apply against the Secretary where the Secretary has previously litigated, and lost, an issue against the same party?

2. Likewise, having previously determined multiple times that coverage of a medical device to treat Plaintiff's extremely lethal form of brain cancer was appropriate, is it arbitrary and

capricious for the Secretary to decide otherwise when the facts and/or circumstances have not changed?

3. In the case at issue here, the Secretary asserts that his regulations (rather than the directives of the Supreme Court) preclude collateral estoppel and that month-to-month differing decisions (where the facts and/or circumstances have not changed) on Plaintiff's life-saving care are not arbitrary and capricious. Plaintiff asserts that those positions are wholly without merit.

4. Tragically, the Plaintiff is suffering from a particularly deadly form of brain cancer, glioblastoma multiforme (GBM)¹, and is seeking coverage for life-saving treatment. In a particularly cruel twist, on a month-to-month basis, the Secretary is forcing the Plaintiff to repeatedly prove that he is entitled to the treatment and the Secretary's decisions differ with no predictable pattern. Thus, the Secretary is playing a game of chance with the Plaintiff's life – maybe this month he will get life-saving treatment – maybe he won't.

II. JURISDICTION

5. This Court has jurisdiction over this action pursuant to 42 U.S.C. §§ 405(g) and 1395ff. Each of the Plaintiffs is filing suit after final decisions of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of their Medicare claims (and, therefore, have exhausted their administrative remedies), the amount-in-controversy is more than \$1,630 (42 U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days of the Secretary's final decisions, as a result of escalation. See 42 C.F.R. § 405.1016(f).

6. Venue is proper in this district pursuant to 42 U.S.C. § 405(g) because this action is being brought in district in which the Plaintiff resides.

¹ Former Senators Edward Kennedy and John McCain also suffered, and died from, this kind of cancer.

III. PARTIES

7. Plaintiff Randall Goldman is an individual and a resident of the State of Texas. Mr. Goldman is eligible for Medicare on the basis of age (or disability) as previously determined by the Secretary.

8. Defendant Alex Azar is sued in his official capacity as the Secretary of Health and Human Services.

IV. LEGAL BACKGROUND

9. Of course, the doctrine of mutual collateral estoppel applies to the government and may bar the government from re-litigating facts/issues the government previously litigated and lost. *See U.S. v. Stauffer Chemical Co.*, 464 U.S. 165 (1984).

10. Moreover, collateral estoppel may be based not only on litigation in federal or state courts but also on proceedings before an agency, when the agency is acting in a judicial capacity. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991), the Supreme Court held that:

We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

11. The application of collateral estoppel to agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Brewster v. Barnhart*, 145 Fed.App'x. 542 (6th Cir. 2005) (SSA ALJ bound by prior work determination).

12. Beyond the application of collateral estoppel and the arbitrary and capricious standard, Plaintiffs also assert that the simple denial of coverage is not supported by substantial evidence, is arbitrary and capricious, and is contrary to law, etc.

V. FACTUAL BACKGROUND

Tumor Treatment Field Therapy (TTFT)

13. Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without treatment, survival is typically three months. Even with traditional forms of treatment, the survival rate at two years after treatment is ~31%, while at five years, only ~5% of patients are living.

14. More recently, treating GBM using alternating electric fields has been developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase the period during which the GBM does not progress, as well as overall survival rates. Indeed, TTFT has proven so effective

that, in late 2014, a randomized clinical trial of TTFT was suspended because it would have been unethical to withhold TTFT treatment from the control group.²

15. In ground-breaking papers published in the Journal of the American Medical Association (JAMA)³ in 2015 and 2017, TTFT was shown to increase the two-year survival rate by more than 38% and to nearly triple the five-year survival rate.⁴

16. As reported, TTFT was the first significant advance in treating GBM in more than a decade. TTFT has become the standard of care for treating GBM and essentially all private insurers cover TTFT. TTFT saves and/or extends GBM patients' lives, in some instances, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It is given a level one recommendation in the National Comprehensive Cancer Network (NCCN) guidelines, *i.e.*, there is consensus, among the experts, based on a high level of evidence, that TTFT is a recommended intervention.

² In much scientific research, study participants are randomly assigned to “control” and “test” groups. The “control” group does not receive the treatment being tested. In contrast, the “test” group does. Proceeding in this way facilitates the determination of which effects, if any, are the result of the tested treatment as opposed to normal variation among the study participants. During the course of a study, interim results are frequently measured to determine whether the study is proceeding as planned and whether any changes are needed. When the interim results indicate that the tested treatment has a significant effect on health or safety, either negative or positive, ethical guidelines dictate that the study should be halted. Thus, if the interim results indicate that the tested treatment was significantly more likely to result in death than the control group, the study would be halted and the treatment no longer given to the “test” group. Likewise, if the interim result indicated that the tested treatment was literally life-saving, the study would be halted and the treatment would be made available to the “control” group. In those circumstances, withholding the treatment from the “control” group would be unethical.

³ The Journal of the American Medical Association (JAMA) is widely regarded as one of the most prestigious medical journal in the United States and the world.

⁴ See Stupp, et al., “MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOLIMIDE VS. TEMOZOLOLIMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL”, JAMA, Vol. 314, No. 23, pgs. 2535-43 (December 15, 2015); Stupp, et al., “EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOLIMIDE VS. MAINTENANCE TEMOZOLOLIMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA”, JAMA, Vol. 318, No. 23, pgs. 2306-2316 (December 19, 2017).

17. The sole supplier of the equipment that delivers TTFT is Novocure, Inc. which manufactures the Optune system. The Optune system is rented on a monthly basis. Thus, after a patient is prescribed the Optune system, they will have monthly claims for Medicare coverage. Sadly, there is no known cure for GBM and patients prescribed TTFT treatment will have to continue that treatment for the rest of their hopefully extended lives.

The Medicare Appeals Process

18. Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5) level appeal process, that can (and typically does) take more than a year. At the first stage, a beneficiary submits a claim. If the claim is denied, the beneficiary can request “redetermination.” If the claim is still denied, the beneficiary can request “reconsideration.” If the claim is still denied, the beneficiary can appeal to an Administrative Law Judge (ALJ). If the ALJ denies the claim, the beneficiary can appeal to the Medicare Appeals Council (MAC). Finally, if the claim is still denied, the beneficiary can file suit in district court.

19. While the statutes and regulations require both ALJs and the MAC to issue decisions within 90 days, those deadlines are routinely missed. Thus, beneficiaries seeking coverage are often thrown into a multi-year effort to obtain final decisions in their cases before they can seek relief in a federal court.

Facts Specific to Mr. Goldman

20. Mr. Goldman has been diagnosed with a GBM and, after other treatment, has been prescribed TTFT.

21. Mr. Goldman has previously received a favorable decision from ALJ Scott Tews in ALJ Appeal No. 1-7718819982 on December 19, 2018 determining that TTFT was medically

reasonable and necessary for him and a covered benefit. The Secretary did not appeal that decision and it has become final.

22. Nevertheless, on January 23, 2019, ALJ McCormick issued a decision in ALJ Appeal No. 1-7884275431 holding that TTFT was not medically reasonable and necessary for Mr. Goldman and denying coverage.

23. Likewise, on July 23 and August 2 and 20, 2019, ALJ Patterson issued decisions in ALJ Appeal Nos. 1-8454636221, 1-8510955262, and 1-8665714599 holding that TTFT was not medically reasonable and necessary for Mr. Goldman and denying coverage.

24. Mr. Goldman timely appealed ALJ McCormick and Patterson's decisions on February 27 and August 20 and 29 and September 20, 2019. When no decision was received within 90 days, pursuant to 42 C.F.R. § 405.1016(f), Mr. Goldman filed notices of escalation on December 31, 2019.

25. On January 22, 2020, the MAC responded that they could not process Mr. Goldman's appeal and that judicial review was authorized.

26. Accordingly, Mr. Goldman is entitled to judicial review.

CAUSES OF ACTION

COUNT I **Violation of 42 U.S.C. §405(g)** (contrary to law)

27. Plaintiff hereby incorporates paragraphs 1-26 herein.

28. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions as contrary to law, as arbitrary and capricious, an abuse of discretion, and unsupported by the evidence, and issue an order finding that Plaintiff's claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT II
Violation of 5 U.S.C. § 706(1)
(unlawfully withheld or unreasonably delayed)

29. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions as unlawfully withheld or unreasonably delayed and unsupported by the evidence, and issue an order finding that Plaintiff's claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT III
Violation of 5 U.S.C § 706(2)(A)
(arbitrary and capricious, abuse of discretion, not in accordance with law)

30. Paragraphs 1-29 are incorporated by reference as if fully set forth herein.

31. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, and issue an order finding that Plaintiff's claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT IV
Violation of 5 U.S.C § 706(2)(C)
(in excess of statutory jurisdiction, authority, or
limitations or short of statutory right)

32. Paragraphs 1-31 are incorporated by reference as if fully set forth herein.

33. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions as in excess of the Secretary's authority and limitations and short of Plaintiff's statutory rights and issue an order finding that Plaintiff's claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT V
Violation of 5 U.S.C § 706(2)(D)
(without observance of procedure required by law)

34. Paragraphs 1-33 are incorporated by reference as if fully set forth herein.

35. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions as done without observance of the procedure required by law and issue an order finding that Plaintiff's claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT VI
Violation of 5 U.S.C § 706(2)(E)
(not supported by substantial evidence)

36. Paragraphs 1-35 are incorporated by reference as if fully set forth herein.

37. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions as not supported by substantial evidence and issue an order finding that Plaintiff's claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff asks that this Court:

A. Enter an order:

(1) finding that the Secretary is collaterally estopped from relitigating whether TTFT treatment for Plaintiff's is a covered benefit;

(2) finding that, in light of the prior decisions granting coverage, the denials at issue in this case are arbitrary and capricious;

(3) finding that TTFT is medically reasonable and necessary for Plaintiff and a covered Medicare benefit;

(4) directing the Secretary to cover the claims at issue in this case;

B. Award attorneys' fees and costs to Plaintiff as permitted by law; and

C. Provide such further and other relief this Court deems appropriate.

Dated: June 25, 2020

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I certify that the above document was served via the Court's CM/ECF system to all counsel of record on June 25, 2020.

/s/ Austin K. Yancy
Austin K. Yancy